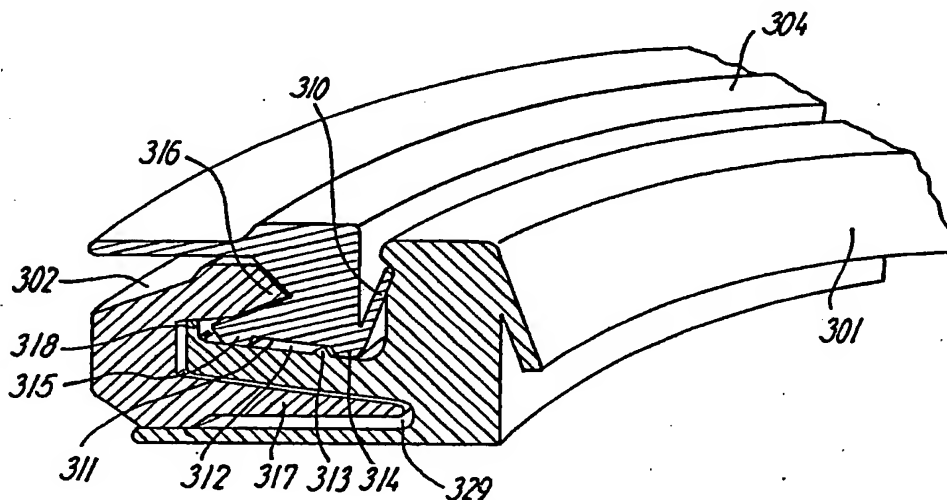




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁵ : A61F 5/448	A1	(11) International Publication Number: WO 91/01118 (43) International Publication Date: 7 February 1991 (07.02.91)
(21) International Application Number: PCT/DK90/00192 (22) International Filing Date: 20 July 1990 (20.07.90) (30) Priority data: 3618/89 21 July 1989 (21.07.89) DK (71) Applicant (for all designated States except US): COLO-PLAST A/S [DK/DK]; Bronzevej 2-8, DK-3060 Espergærde (DK). (72) Inventor; and (75) Inventor/Applicant (for US only) : OLSEN, Hans [DK/DK]; Lindholmsvej 35, DK-2700 Brønshøj (DK). (74) Agent: HOFMAN-BANG & BOUTARD A/S; Adelgade 15, DK-1304 Copenhagen K (DK).		(81) Designated States: AT (European patent), AU, BE (European patent), BR, CA, CH (European patent), DE (European patent)*, DK (European patent), ES (European patent), FR (European patent), GB (European patent), IT (European patent), JP, LU (European patent), NL (European patent), SE (European patent), SU, US. Published <i>With international search report.</i>

(54) Title: AN OSTOMY COUPLING**(57) Abstract**

In an ostomy coupling comprising a patient part with a neck and a bag part adapted to be coupled in tight-fitting relationship with the neck of the patient part, a locking ring for mutually retaining these two parts is elastically deformable and movably retained with respect to the patient part so that it is deformable between a first position and a second position, where the coupled parts are mutually loosely connected and mutually locked, respectively. The locking ring is provided with two locking mechanisms independent of each other, one of which is activated when changing the ostomy bag, and the other secures the locking ring to the patient part. Conical faces for axial engagement facilitate centering when assembling the parts.

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An ostomy coupling

The present invention relates to an ostomy coupling comprising a first part with a neck, a second part with a collar adapted to be coupled in tight-fitting relationship with the neck of the first part, one of said parts being intended to be attached to a patient, the other part being secured to a collection bag, and a locking ring for mutually retaining said parts.

The invention is primarily constructed as a lockable coupling for retaining ostomy equipment, such as bags for collection of evacuations from surgically formed, artificial intestinal orifices, and for retaining closure-like locking devices for such artificial bodily orifices, but it is also suited for retaining ostomy, incontinence, wound and fistula drainages, including retaining bags for collection of urea from incontinent natural or artificial urinary orifices.

Such couplings are usually annular and the part intended to be attached to a patient (in the following called the patient part) is often provided with a plate or flange applied with an adhesive by which the patient part is adhered to the patient's skin and which is generally changed at an interval of several days. The second part of the coupling, which is secured to a bag for collecting faeces, in the following called the bag part, must for obvious reasons be completely tight-fitting to the patient part.

Manipulation of the coupling parts during assembling and disassembling may cause great pain especially to newly operated ostomy patients, and consequently it is important that such manipulation transfers as few and small force.

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loads as at all possible to the patient.

Consequently, it is desirable to provide a coupling of the kind described being provided with a locking mechanism so that assembling and disassembling may be performed without causing heavy loads, while the coupling parts are retained together by a locking mechanism which can be brought into and out of engagement in an easy way without transferring any appreciable force to the patient. It is furthermore important that the coupling besides the patient part and the bag part comprises no other loose or separate parts, so that assembling and disassembling can be performed quickly, in a simple and safe way.

It is the object of the present invention to provide such an ostomy coupling.

According to the invention the object is achieved by a construction as stated in the characterizing portion of claim 1.

By the locking ring being deformable and movably retained with respect to one of the parts so that it is deformable between a first position and a second position, where the coupled parts are mutually loosely connected and mutually locked, respectively, it is achieved that the locking ring and the part to which it is retained, by the user is perceived as one single part. The locking ring can then be so positioned that in the position in which the coupled parts are mutually loosely connected it can by one single movement be made to assume the other position in which the parts are mutually locked and vice versa. By means of such an ostomy coupling comprising three parts the correct positioning of the locking ring is ensured, and the patient only needs to place the bag part correctly relatively to the patient part without worrying about

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whether also the locking ring is correctly positioned, whereafter the parts are locked with the locking ring.

5 By the locking ring, as stated in claim 2, being elastically deformable it is achieved that when released it is capable by itself of assuming the position in which the coupled parts are mutually loosely connected. The patient consequently only needs to perform one single release operation before the coupled parts can be disassembled.

10 By an ostomy coupling according to claim 3 the locking ring can be released from that part to which it is secured, and similarly during manufacture it can in a simple way be positioned on and retained with respect to
15 the same part. By the two locking mechanisms being independent of each other the patient in particular obtains the advantage that the second locking mechanism is not unintentionally activated when operating the first locking mechanism. Thus it is ensured that the locking ring is
20 constantly retained with respect to the coupling part in question.

As stated in claim 4 it is advantageous to retain the locking ring to the patient part, the latter as mentioned
25 being changed less frequently than the bag part.

By the embodiment of the complementary engagement faces of the bag part and the locking ring as stated in claim 5 it is achieved that the bag part in its locked state can be
30 retained in a minutely preselected position, and that in case of force load, e.g. the force of gravity from a full bag, it will not undergo deformation or tilt, but remain centred, and thus at all times ensure a tight-fitting coupling.

35 When the first and second part of the coupling as stated

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in claim 6 have complementary engagement faces adapted for axial engagement, no frictional force has to be surmounted during assembling and disassembling, which e.g. is the case with faces having substantially radial engagement.

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This ensures the lowest possible force load and pain for the patient. These axial engagement faces can advantageously be slightly conical, which is stated in claim 7. Hereby is achieved a centering effect during assembling.

10

A particularly efficient seal at the engagement faces is achieved when at least one of these faces, as stated in claim 8, is provided with one or more circular ribs, such a rib by elastic deformation easily being capable of adapting itself to small unevennesses, if any, in the opposite engagement face, thus ensuring an efficient seal.

15

In order to avoid spilling of faeces when changing bag, the engagement face of the patient part may along its periphery be provided with an axially outwardly projecting edge, which will act as a barrier. This is stated in claim 9.

20

In claim 10 is stated that the locking ring has radially resilient tongues. When changing bag these tongues will ensure the centering of the locking ring in relation to the patient part, whereby the positioning of the bag part is facilitated.

25

As stated in claim 11 the locking ring can be retained to one of the coupling parts by means of flexible straps. Hereby the locking ring and the coupling part in question can be integrally moulded, and by suitable choice of material and dimensions the straps will be able to contribute to the elastic resiliency of the locking ring.

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In the following the invention is described in more detail, reference being made to the drawing in which

- 5 fig. 1 shows a first embodiment of the invention,
- fig. 2 shows a perspective view of a radial section of a
 part of the coupling as shown in fig. 1,
- 10 fig. 3 shows the part of the coupling which is intended
 to be attached to a patient, and which is shown in
 fig. 2,
- fig. 4 shows another embodiment of the invention,
- 15 fig. 5 shows a perspective view of a radial section of a
 part of the embodiment shown in fig. 4,
- fig. 6 shows a perspective view of a radial section of a
20 preferred embodiment of the invention,
- fig. 7 shows the locking ring in the embodiment shown in
 fig. 6 in a pre-locked position,
- 25 fig. 8 shows the locking ring in fig. 7, but in locked
 position,
- fig. 9 shows a part of the locking ring in a completely
 unlocked position,
- 30 fig. 10 shows a section through the locking mechanism of
 the locking ring in the pre-locked position,
- fig. 11 shows a section through the locking mechanism of
35 the locking ring in the locked position,

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fig. 12 and 13 show parts of an alternative embodiment of the locking ring in pre-locked and locked position, respectively,

5 fig. 14 shows a preferred embodiment of the locking ring according to the invention in completely unlocked position, and

10 fig. 15 shows the coupling in fig. 6, but provided with a so-called convex ring.

15 Figs. 1-3 show a first embodiment of the invention having an annular patient part 101 with a short neck and being secured to a not shown plate or flange adapted for being attached to the patient's skin around an ostomy orifice by means of an adhesive. A locking ring 102 is here by means of flexible straps 103 connected to a ring 104 being secured to a bag not shown for collecting faeces. The locking ring 102 and the annular bag part 104 are positioned at either side of engagement taps 105 constituting parts of the patient part 101. The locking ring 102 and the bag part 104 are shown in fig. 2 in a pre-locked position allowing the bag part 104 with the locking ring 102 and the patient part 101 to be assembled and disassembled. The locking ring 102 is flexible and can from the position shown in fig. 2 be tightened so that a radially inwardly directed protrusion 106 on the inner side of the locking ring 102 engages with a complementary, radially outwardly directed protrusion 107 on the engagement taps 105. The engagement taps 105 are flexible and have radially inwardly directed protrusions 108 which engage with complementary and radially outwardly directed protrusions 109 on the bag part 104. Hereby the bag is fixed relatively to the patient part 101, thus especially ensuring that they cannot be separated.

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Figs. 4 and 5 show a variant of the above embodiment. A locking ring 202 is here by means of flexible straps 203 secured to an annular patient part 201. The locking ring 202 is here shown in a locked state, in which an annular bag part 204 is retained in position in relation to the patient part 201 so as to be inseparable.

The preferred embodiment of the invention shown in fig. 6 has an annular patient part 301 with a short neck and at its under side being adapted for being secured onto the adhesive plate or flange, by which the patient part 301 is positioned on the patient's skin around an ostomy orifice. An annular bag part 304 is adapted at its upper side for being secured to a not shown bag for collection of faeces from the ostomy orifice. An elastic resilient locking ring 302 is here shown in a locked position in which it retains the bag part 304 in position relatively to the patient part 301.

The seal between the bag part 304 and the patient part 301 of the coupling is constituted partly by a radially flexible lip ring 310 which abuts against a corresponding face on the patient part 301, partly by axial engagement between an engagement face 311 on the bag part 304 and an engagement face 312 on the patient part 301. The engagement face 312 of the patient part is here shown with an annular rib 313, and similarly also the engagement face of the bag part is shown with two such ribs 314 and 315. As a result of force load from the locking ring 302 in axial direction these ribs ensure a more reliable seal, as the axial contact faces are thus relatively small so that the axial coupling force will somewhat deform the ribs, and consequently small unevennesses, if any, on the contact faces are smoothened out as a consequence of the resulting elastic deformation of the materials.

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It is further seen that the engagement faces 311 and 312 are substantially conical with a relatively large opening angle. The conical shape of the engagement faces contribute to the centering of the bag part 304 in relation to the patient part 301 when assembling these parts, so that the risk of excentric assembly of the parts is significantly reduced.

The locking ring has an inwardly projecting part 316 being shaped as an outwardly open V, and which when tightening and locking the locking ring engages with a corresponding recess in the bag part. When pressing the locking ring this V-shape produces the necessary axial coupling force between the bag part 304 and the patient part 301. Further, this shape also provides support for the bag part so that a possible force load from e.g. a full ostomy bag cannot deform the locking ring, whereby complete seal and maximum user comfort are ensured at all times.

From fig. 6 it is also seen that along the periphery of the engagement face 312 of the patient part 301 there is an axially outwardly projecting edge 318 which during bag changing prevents or at least significantly reduces spilling of faeces.

The locking effect, i.e. the tightehing of the bag part 304 and the patient part 301 is derived from the locking ring 302. In figs. 7-9 it is seen that the locking ring 302 is broken by an almost radial cut so as to be capable of assuming the three positions shown in figs. 7-9, respectively. Fig. 7 shows the locking ring in a pre-locked position, which is the position it is in when the coupling is supplied to the user and when being attached to the user's body, and which permits changing of the ostomy bag, as the coupled parts here are mutually loosely connected. Fig. 8 shows the locking ring 302 in a locked

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position in which it is also shown in fig. 6, and in which the bag part 304 is retained in position in relation to the patient part 301. Fig. 9 shows the locking ring 302 in a completely open position, which position the locking ring has during manufacture by moulding, and in which it can be positioned on the patient part 301. The locking ring 302 is preferably moulded in an elastic resilient material and will thus naturally seek to assume the completely open position shown in fig. 9. When locking mechanisms for the locked and pre-locked position, respectively, of the ring are released, the locking ring will consequently by itself spring open and assume the pre-locked or the completely unlocked position, respectively.

In each of the three positions of the locking ring, the pre-locked, the locked and the completely unlocked position, respectively, it has three different diameters.

As is seen from fig. 6 the locking ring 302 has an inwardly projecting part or edge 317 which has a smaller internal diameter than that of the part 316 of the locking ring. These internal diameters are so adapted that in the pre-locked position of the ring in fig. 7, the diameter of the part 316 of the locking ring which retains the bag part, is increased precisely so much compared to the locked position that the bag part 304 and the patient part 301 can easily be assembled and disassembled by a mutual axial movement. In this pre-locked position of the locking ring, the part 317 of the locking ring is still in engagement with the corresponding recess or groove 325 in the patient part 301, and the locking ring is thus retained on the patient part.

Not until the locking ring 302 is opened to assume its completely unlocked position in fig. 9 can also the

- 10 -

locking ring be released from the patient part 301.

Fig. 10 shows a section through the pre-locked locking mechanism of the locking ring along the line X-X in fig. 7, and fig. 11 shows a section through the locked locking mechanism of the locking ring along the line XI-XI in fig. 8. On a radially outwardly projecting protrusion 331, the locking ring is provided with two elastic, axially resilient flaps 319 which at their tips have axially outwardly projecting hooks 320, which in the pre-locked position in fig. 10 abut against corresponding inwardly directed hooks 321, and in the locked position in fig. 11 abut against a hook 322. The hooks 321 and 322 are provided on a radially outwardly projecting protrusion 332. In order to activate this locking mechanism so as to pass from the pre-locked position in fig. 10 to the locked position in fig. 11 the two protrusions 331 and 332 of the locking ring are pressed together, and one of the hooks 320 enters into a clicking-engagement with the hook 322. Through an opening 323 it is possible by a slight touch of a finger to disengage the hooks 320 and 322, whereby the locking mechanism due to its resiliency reassumes the pre-locked position in fig. 10.

In order to release the locking mechanism completely, the hooks 320 must be released from the hooks 321, and with a suitable construction of the hooks this is done in that the protrusion 331 with the flaps 319 by a radial movement are lifted free of the hooks 321 so that the locking ring assumes the unlocked position shown in fig. 9.

Fig. 14 shows the preferred embodiment of the locking ring according to the invention in its completely unlocked state. A flap 324 here corresponds to the flaps 319 in figs. 10 and 11, and the flap 324 has an axially outwardly projecting hook 325 corresponding to the hooks 320 in

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figs. 10 and 11. Further, the locking ring in fig. 14 has on each separate one of the protrusions 331 and 332 two hooks 326 and 327. In the pre-locked position of the locking ring these hooks are in mutual engagement, and the locking ring may be made to assume its completely unlocked position in that the hook 326 by a radial movement is released from the hook 327. From the completely unlocked position the locking ring is easily made to assume both the pre-locked and the locked position by pressing the locking ring.

In fig. 14 it is further seen that some of the parts 317 of the locking ring are provided with radially inwardly projecting resilient tongues 328, the tips of which lie on a circle having a diameter which is smaller than that of the parts 317. These resilient tongues 328 will also in the pre-locked position of the locking ring be in radial contact with the bottom of the annular groove 329 in the patient part 301, and thus also in the pre-locked position of the locking ring centre the locking ring.

Figs. 12 and 13 show a fourth embodiment of the locking mechanism of the locking ring. A locking ring 402 is open along a radial cut, and on both sides of the cut two rocker arms 403 and 404 are hingedly secured. By hinges 408, provided as thin material bridges, the rocker arms 403 and 404 are mutually connected as well as connected to the locking ring 402 on respective sides of the radial cut. The locking ring 402 is in fig. 12 shown in an open position allowing change of ostomy bag, and in fig. 13 in a locked position in which a not shown ostomy bag can be retained in position in relation to a not shown patient part. The rocker arm 404 has a hook 405 which passes into engagement with a hook 406 on the locking ring 402.

The locking mechanism is released from the locked position.

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shown in fig. 13 by touching a tap 407 with a finger so that the hooks 405 and 406 pass out of engagement. The hooks 405 and 406 may be so formed that the tap 407 must be activated either radially or axially in order to
5 release the hooks 405 and 406 from their mutual engagement.

Finally, fig. 15 shows how the coupling according to the invention can be combined with a so-called convex ring
10 330. A convex ring is often used in connection with ostomies which do not project from the body, but lie in the same plane or even below surface level, and it serves to keep the adhesive plate fixed to the skin so as to prevent faeces material from seeping out from below.

15 The coupling according to the invention may be made of ordinary plastic materials used for couplings in connection with ostomy and bandaging purposes, e.g. polyethylene or EVA-materials. To ensure that the locking ring is flex-
20 ible and elastically deformable, but not stretchable, it may e.g. be made of a plastic material having a somewhat higher E-modulus, e.g. polypropylene or ABS, or be provided with a fibre reinforcement of such materials.

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P a t e n t C l a i m s :

1. An ostomy coupling comprising
- 5 a first part with a neck,
- a second part with a collar adapted to be coupled in
10 tight-fitting relationship with the neck of the first
 part,
- one of said parts being intended to be attached to a
 patient, the other part being secured to a collection bag,
 and
- 15 a locking ring for mutually retaining said parts,
- c h a r a c t e r i z e d in that the locking ring is
 deformable and is movably retained with respect to one of
20 the parts so that it is deformable between a first
 position and a second position, where the coupled parts
 are mutually loosely connected and mutually locked,
 respectively.
- 25 2. An ostomy coupling according to claim 1, c h a r -
 a c t e r i z e d in that the locking ring is elastically
 deformable.
- 30 3. An ostomy coupling according to claims 1-2, c h a r -
 a c t e r i z e d by further including a first locking
 mechanism for the first position and the second position
 of the locking ring, and a second locking mechanism which
 is independent of the first locking mechanism and is
 adapted to retain and release the locking ring,
35 respectively, with respect to said one of the parts.

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4. An ostomy coupling according to claims 1-3, c h a r -
a c t e r i z e d in that the locking ring is retained
with respect to that of the parts which is intended to be
attached to a patient.

5

5. An ostomy coupling according to claim 4, c h a r -
a c t e r i z e d in that that of the parts which is
secured to a collection bag and the locking ring have
complementary engagement faces in the form of radially
outwardly open V.

10

6. An ostomy coupling according to claims 1-5, c h a r -
a c t e r i z e d in that the first part and the second
part have complementary engagement faces adapted for axial
engagement.

15

7. An ostomy coupling according to claim 6, c h a r -
a c t e r i z e d in that the engagement faces are
conical.

20

8. An ostomy coupling according to claims 6-7, c h a r -
a c t e r i z e d in that at least one of the engagement
faces is provided with one or more ribs.

25

9. An ostomy coupling according to claims 6-8, c h a r -
a c t e r i z e d in that the engagement face of the part
intended for attachment to a patient has an axially out-
wardly protruding edge along its periphery.

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10. An ostomy coupling according to claims 4-9, c h a r -
a c t e r i z e d in that the locking ring has radially
resilient tongues for cooperation with the patient part.

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11. An ostomy coupling according to claims 1-2, or 4-10,
c h a r a c t e r i z e d in that the locking ring is
retained with respect to one of the parts by means of
flexible straps.

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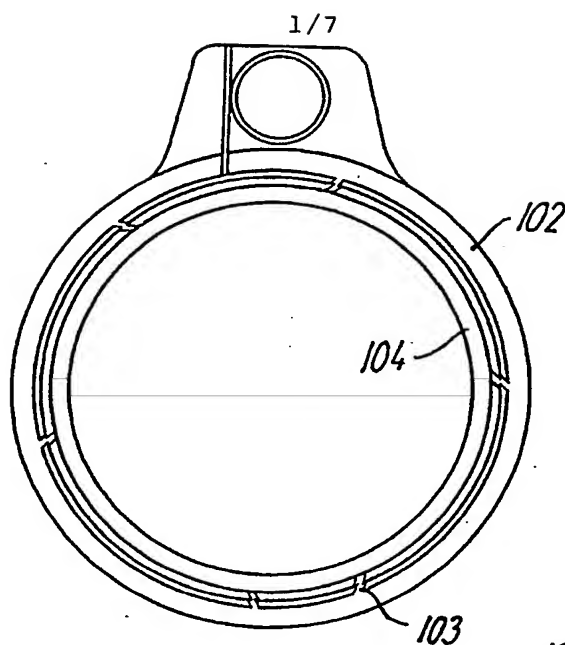


FIG. 1

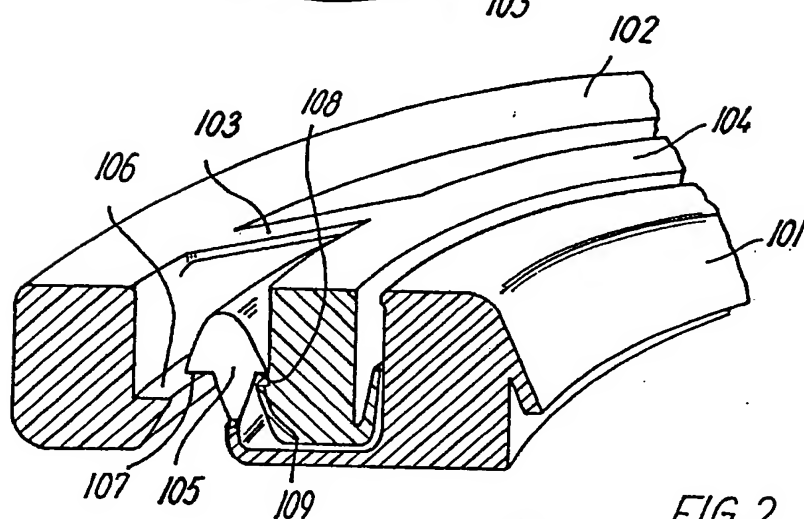


FIG. 2

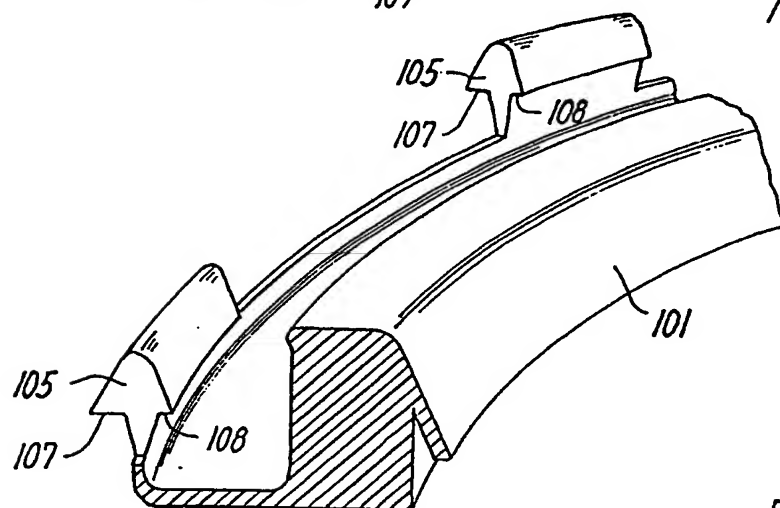


FIG. 3

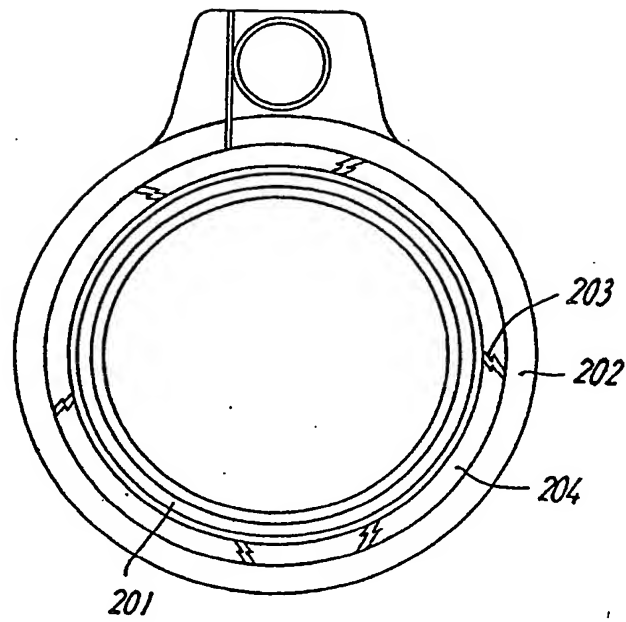


FIG. 4

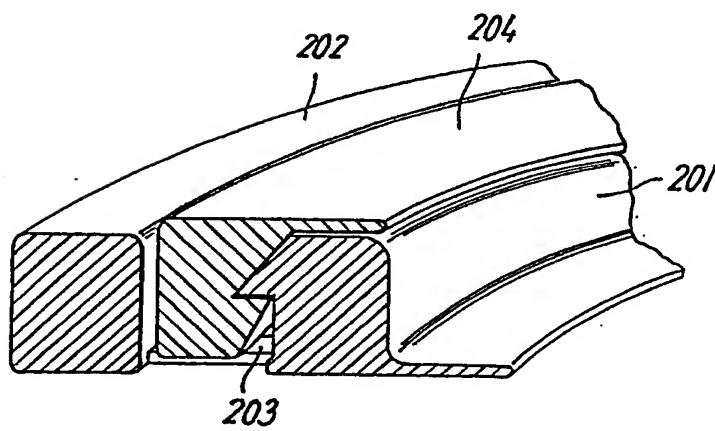


FIG. 5

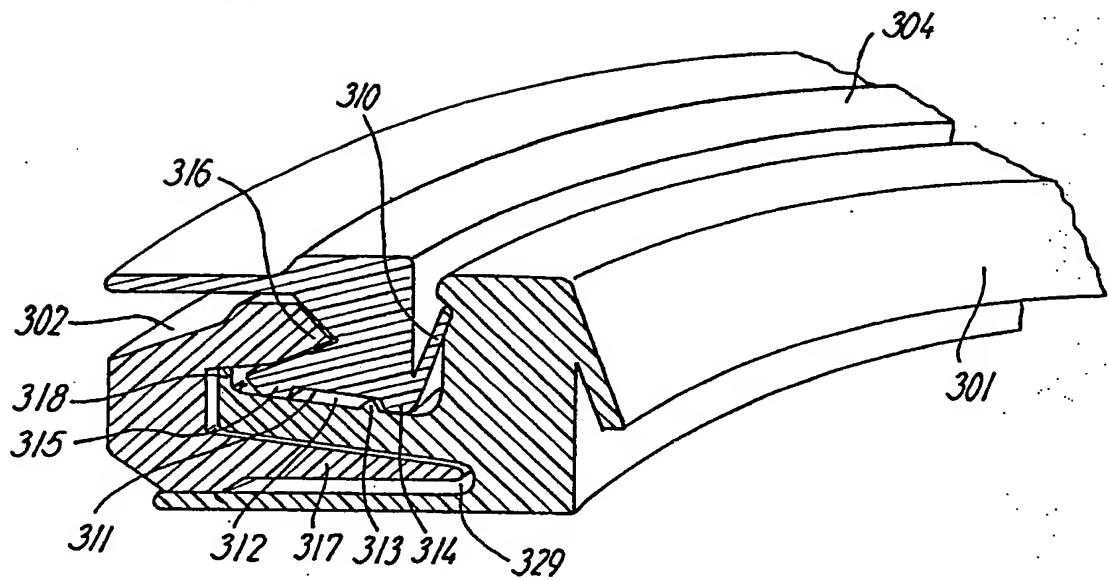


FIG. 6

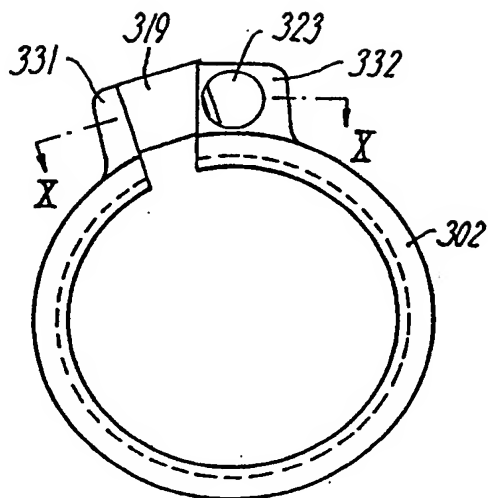


FIG. 7

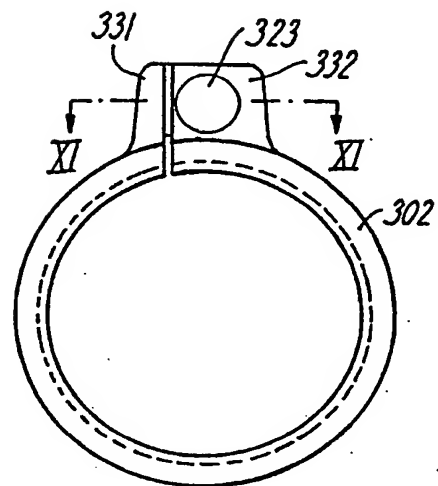


FIG. 8

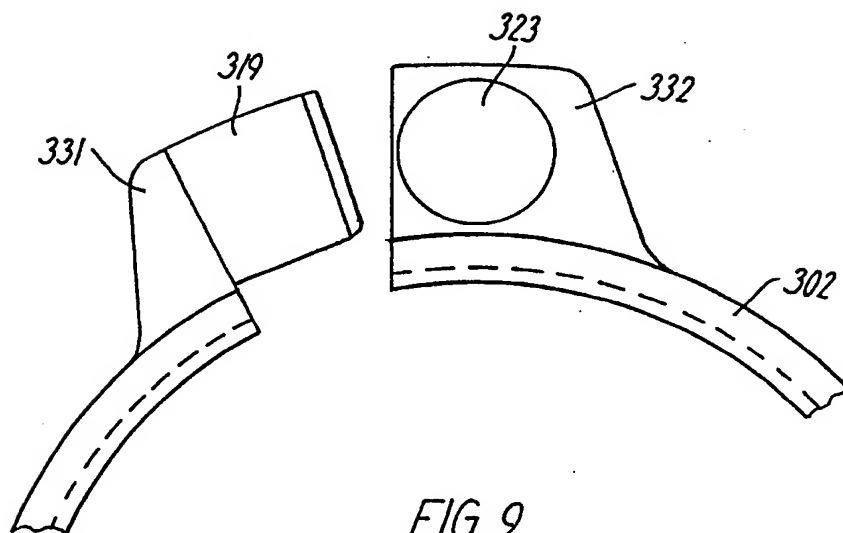
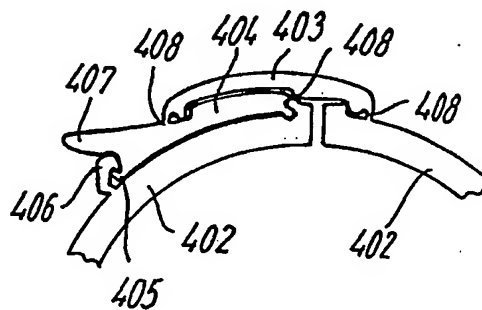
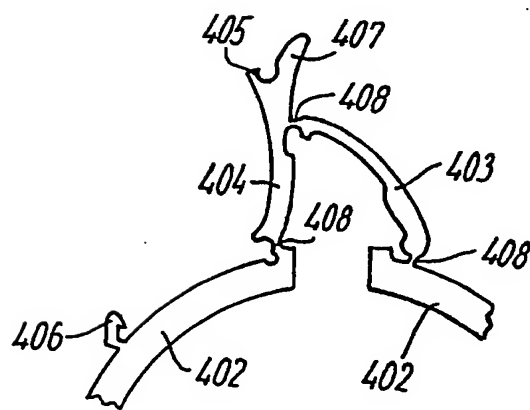
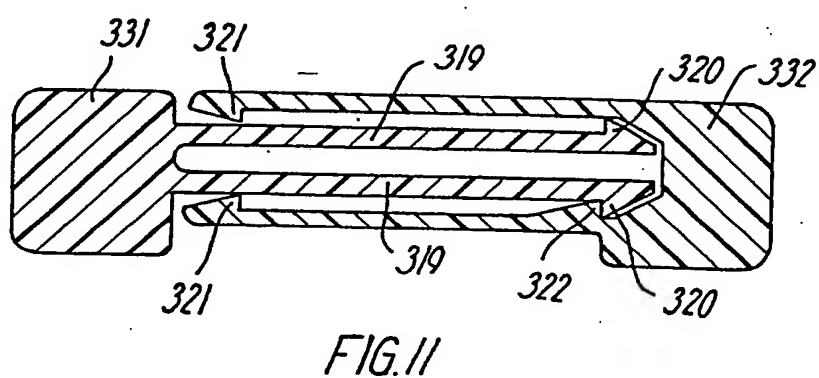
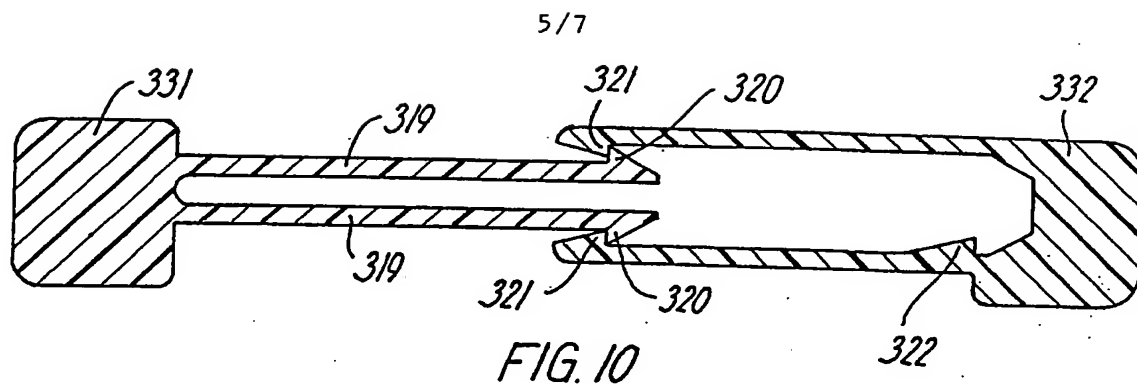


FIG. 9



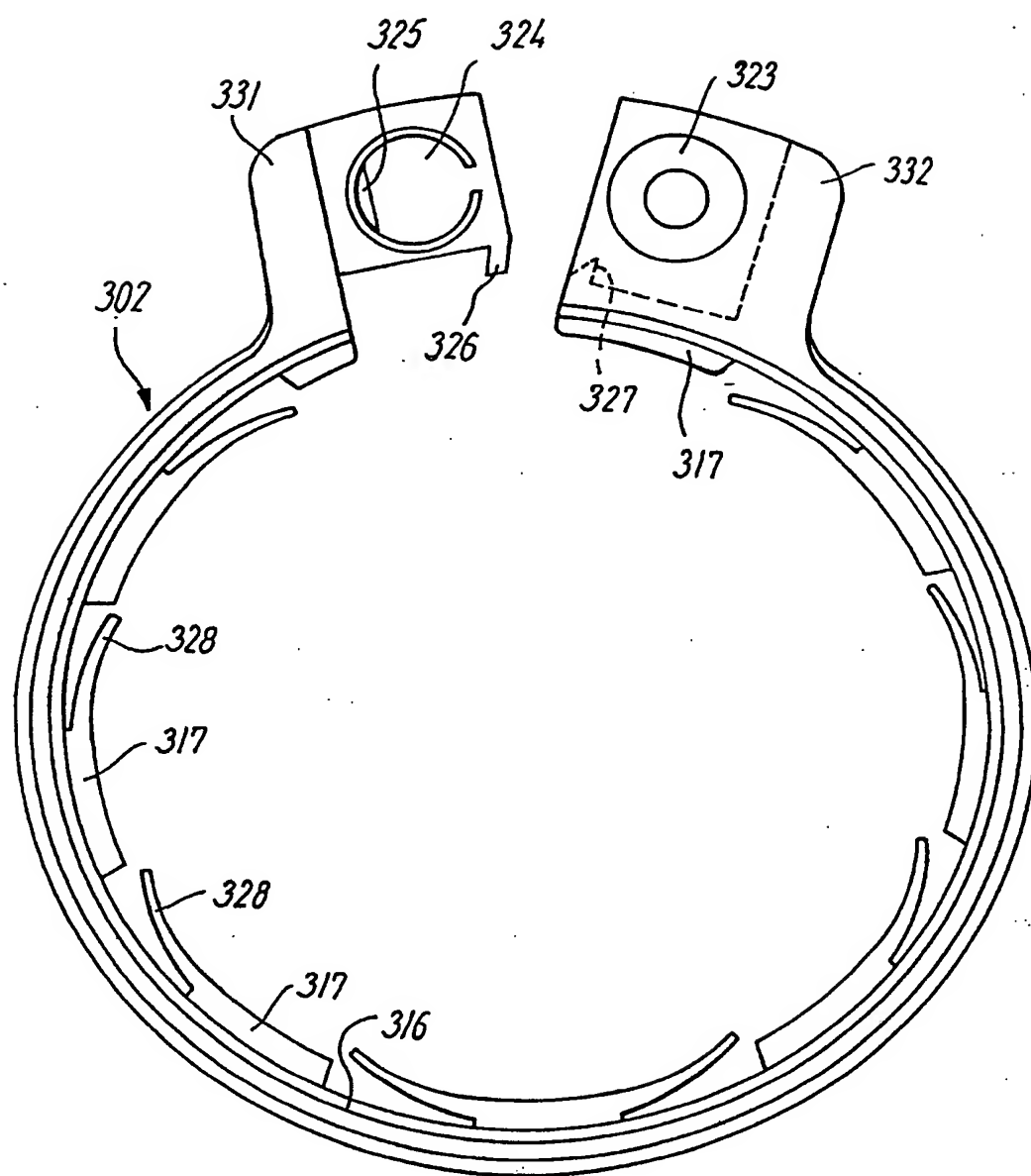
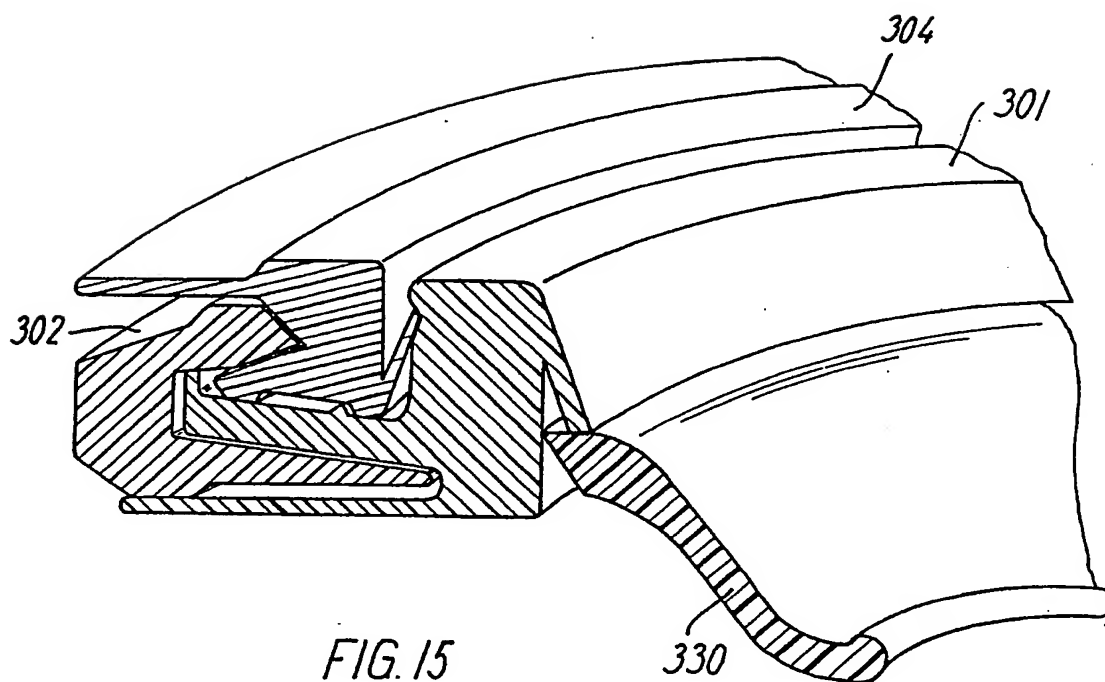


FIG. 14



INTERNATIONAL SEARCH REPORT

International Application No PCT/DK 90/00192

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶		
According to International Patent Classification (IPC) or to both National Classification and IPC		
IPC5: A 61 F 5/448		
II. FIELDS SEARCHED		
Minimum Documentation Searched ⁷		
Classification System	Classification Symbols	
IPC5	A 61 F	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in Fields Searched ⁸		
SE,DK,FI,NO classes as above		
III. DOCUMENTS CONSIDERED TO BE RELEVANT⁹		
Category *	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³
X	GB, A, 2201345 (CRAIG MEDICAL PRODUCTS LIMITED) 1 September 1988, see the whole document --	1-2,4-6, 9
A	EP, A1, 0255310 (CRAIG MEDICAL PRODUCTS LIMITED) 3 February 1988, see figures 4-5 --	1,4-6,9
A	NO, B, 119437 (L. NYGAARD) 19 May 1970, see the whole document --	1-2
A	DK, B, 134263 (DANSK COLOPLAST A/S) 11 October 1976, see the whole document --	1
<p>* Special categories of cited documents:¹⁰</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance, the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance, the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>"&" document member of the same patent family</p>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
25th October 1990	1990 -10- 26	
International Searching Authority	Signature of Authorized Officer	
SWEDISH PATENT OFFICE	Leif Karnsäter	

II. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)		
Category *	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No
A	DE, B, 1105558 (FA. HEINRICH CAROLI) 27 April 1961, see the whole document --	1
P	GB, A, 2215212 (SMITHS INDUSTRIES PUBLIC LIMITED COMPANY) 20 September 1989, see the whole document --	1-4,6,9
A	US, A, 4623338 (LARSON) 18 November 1986, see figure 4 -- -----	1

**ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO. PCT/DK 90/00192**

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the Swedish Patent Office EDP file on **90-09-27**. The Swedish Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

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